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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/035,708 03/05/98 ZEMLAN

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HM22/0723

EXAMINER

HAYES, R

ART UNIT	PAPER NUMBER
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1647

*25*

DATE MAILED: 07/23/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

<b>Office Action Summary</b>	Application No. <b>09/035,708</b>	Applicant(s) <b>Zemlan et al</b>
	Examiner <b>Robert C. Hayes</b>	Art Unit <b>1647</b>



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1)  Responsive to communication(s) filed on May 11, 2001

2a)  This action is FINAL.      2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

#### Disposition of Claims

4)  Claim(s) 1-15, 17-27, and 29-31 is/are pending in the application.

4a) Of the above, claim(s) 1-13, 21, and 22 is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 14, 15, 17-20, 23-27, and 29-31 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claims 1-15, 17-27, and 29-31 are subject to restriction and/or election requirement.

#### Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved.

12)  The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)  All b)  Some\* c)  None of:

1.  Certified copies of the priority documents have been received.
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

15)  Notice of References Cited (PTO-892)

18)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_

16)  Notice of Draftsperson's Patent Drawing Review (PTO-948)

19)  Notice of Informal Patent Application (PTO-152)

17)  Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_

20)  Other: \_\_\_\_\_

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## **DETAILED ACTION**

### ***Request for Continued Examination***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/11/01 has been entered.
2. The amendment filed 5/11/01 has been entered. Note the oath remains unsigned.
3. The rejection of claims 19-20 under 35 U.S.C. 112, first paragraph, as containing new matter is withdrawn due to the amendment of the claims.
4. The rejection of claims 14-15, 17-20, 23-27 & 29-30 under 35 U.S.C. 112, first paragraph, for lack of enablement is withdrawn due to the amendment of the claims to now structurally define tau.
5. The rejection of claims 19-20 under 35 U.S.C. § 112, second paragraph, as being indefinite is withdrawn due to the amendment of the claims.

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6. The rejection of claims 17-20 under 35 U.S.C. § 112, second paragraph, as being indefinite for providing no proper antecedent basis for the recitation, “said *at least one isoform* of said tau protein”, is withdrawn due to the amendment of the claims.

7. Applicant's arguments filed 5/11/01 have been fully considered but they are not deemed to be persuasive.

8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

9. Claims 14-15, 17-18, 23-27 & 29-30 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons made of record in Paper #17 and as follows.

No proper antecedent basis nor conception within context of that disclosed within the specification at the time of filing the instant application still remains apparent for the recitation, “fragments thereof” of Goedert's tau protein of SEQ ID NO:1, versus the *specific* “fragment comprising the peptide sequence including the amino acids from serine199 to serine396 of tau

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protein" of SEQ ID NO:1, as contemplated on page 5 of the specification; thereby, still constituting new matter.

10. Claims 14-15, 17-20, 23-27 & 29-31 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite and incomplete for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In particular, the claimed methods are incomplete because it is not recited that the detection of axonally-derived protein bound to the monoclonal antibody determines the presence of axonal damage in the CNS, as recited in the preamble. It further appears necessary that claim 15 needs to be incorporated into base claims 14 & 31.

Lastly, it is ambiguous why a Markush group is necessary in base claims 14 & 31, since the sole "isoform of tau" is now only that of SEQ ID NO:1.

11. Claims 17 & 24 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The metes and bounds of "less than 50 kDa" is unknown and encompasses zero molecular weight; thereby, being ambiguous.

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12. Claim 30 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 30 recites the limitation of "a patient with a neurological disease..." . There is insufficient antecedent basis for this limitation from amended base claim 14.

13. Claims 14-15, 17-20, 23-27 & 29-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Vandermeeren et al (WO 94/13795), for the reasons made of record in Paper #s 12 & 17, and as follows.

In contrast to Applicants' assertions on pages 6-7 of the response, Vandermeeren et al. teach all structural limitations of "(a) obtaining CSF..." and "(b) treating said sample of CSF with at least one monoclonal antibody...", as recited in the claims, in which tau inherently is an "axonally-derived protein" of SEQ ID NO:1, by definition (i.e., as it also relates to new claim 31). Note again that Vandermeeren et al. specifically disclose that tau "is abundantly present in the axonal compartment of these neurons". In addition, as Applicants' correctly point out, Vandermeeren teach using monoclonal antibodies for detecting Alzheimer's Disease, etc., in which Alzheimer's Disease, etc. (e.g., as it especially relates to claim 30) is a well known example of "primary neuronal injuries", etc. as now recited in the claims, or for "traumatic CNS injury" as argued on page 7 of the response; for example, within the CNS basal forebrain cholinergic neurons, whose dysfunction/trauma/neuronal injury characterizes this disease state, as previously made of record. Therefore, Applicants' arguments are moot.

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14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (703) 305-3132. The examiner can normally be reached on Monday through Thursday, and alternate Fridays, from 8:30 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Robert C. Hayes, Ph.D.  
July 17, 2001

*Gary L. Kunz*  
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